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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,552	02/12/2004	Daniel A. Hammer	UPN-4290	6019

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WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,552	HAMMER ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-184* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-184* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 106, drawn to a polymersome comprising a plurality of amphiphilic copolymers and an emissive agent, classified in class 424, subclass 9.1.

II. Claims 107 – 130, drawn to a method of delivering an agent to a biological situs, classified in class 604, subclass 19.

III. Claims 131 – 152, drawn to a method of ascertaining the presence of a disease state in an organism, classified in class 600, subclass 300.

IV. Claims 153 – 165, drawn to an *in vivo* method of diagnostics or imaging, classified in class 600, subclass 407.

V. Claims 166 – 169, drawn to an *in vitro* method of diagnostics, classified in class 250, subclass 330.

VI. Claims 170 – 171, drawn to a method for histological labeling, classified in class 435, subclass 40.51.

VII. Claims 171 – 184, drawn to a method of modulating the emission properties of a visible or NIR emissive agent, classified in class 422, subclass 82.05.

NOTE: In addition to the elected Group above, applicant is requested to elect a *specific* emissive agent from the distinct group thereof as set forth in the claims (e.g. claims 4, 6, 7, 8, or 9; or 55, 56, 57, 58, 59; etc.) to which the elected Group will be limited. The

different structures included therein are a very diverse set and are independent and distinct structures, including porphyrin, rhodamine 101, DODC iodide, coumarin 1, croconium dye, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect *specific* moieties related to R_A and R_B from the distinct group thereof as set forth in the claims if porphyrin is elected as the emissive agent (e.g. claims 17 or 71; etc.) to which the elected Group will be limited. The different structures included therein are a very diverse set and are independent and distinct structures, including H, alkyl, $C(R_c)=C(R_D)(R_E)$, where R_c, R_D, R_E are Cl, Br; peptide, saccharide, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a *specific* linker by which covalently bound emissive moieties are linked from the distinct group thereof as set forth in the claims (e.g. claims 12 or 14; or 62 or 63; etc.) to which the elected Group will be limited. The different linkers included therein are a very diverse set and are independent and distinct structures, including carbon-carbon double bonds, polyvinyl, furanyl, di(thiophenyl), imine, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a *specific* hydrophobic polymer from the distinct group thereof as set forth in the claims (e.g. claims 41 or 42; 97 or 98, etc.) to which the elected Group will be limited. The different

structures included therein are a very diverse set and are independent and distinct structures, including polyethylethylene, poly(butadiene), poly(β-benzyl-L-aspartate), etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a *specific* block copolymer from the distinct group thereof as set forth in the claims (e.g. claims 45, 101, etc.) to which the elected Group will be limited. The different structures included therein are a diverse set and are independent and distinct structures, including poly(ethylene oxide)-polyethylethylene, poly(ethylene oxide)-poly(lactic acid), etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a *specific* targeting moiety from the distinct group thereof as set forth in the claims (e.g. claims 77, 159, etc.) to which the elected Group will be limited. The different structures included therein are a very diverse set and are independent and distinct structures, including carbohydrate, protein, nucleic acid, organic compounds, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of delivering an agent to a biological situs as claimed can be practiced with another materially different product. For example, a drug can be delivered to a desired biological site using magnetically targeted drug delivery methods.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of ascertaining the presence of a disease state as claimed can be practiced with another materially different product. Testing for the presence of various diseases is known, such as a rapid strep test for determining the presence of infection with bacterial infection.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process

for using the product in a method of diagnostics or imaging as claimed can be practiced with another materially different product. For example, MRI imaging can be performed with Gd-DOTA complexes or superparamagnetic iron oxides.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of *in vitro* diagnosis as claimed can be performed with another materially different product. For example, cancer cells can be diagnosed *in vitro* using various markers.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of using the product for histological labeling as claimed can be performed with various dyes, such as congo red or eosin, for example.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product

as claimed can be used in a materially different process, such as for *in vivo* diagnostics or imaging.

Inventions II – III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation because the method of imaging requires an instrument optically coupled to a light source.

Inventions II – IV, VI and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation because the methods of Groups III – V and VII are practiced *in vivo*, while the method of Group VI is practiced *in vitro*.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation because the method of histological labeling requires contacting the polymersome with cells, while the method of modulating the emission properties of an emissive agent does not.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to patentably distinct species: emissive species, emissive species linkers, R_A and R_B moieties if porphyrin is elected as the emissive species, hydrophobic polymers; block copolymers, and targeting moieties. The species are independent or distinct because of their different structures which control the classification.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call was not made to request an oral election to the above restriction requirement because of the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. NOTE: This disclosed species will name a single *specific* emissive species, emissive species linker, R_A and R_B moieties if porphyrin is elected as the emissive species hydrophobic polymer, block copolymer, and targeting moiety. An exemplified species should be elected to show clear support in the specification for the elected species.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Potential Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER